



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1557d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail

Return Receipt Requested

July 26, 2001

Charles Pfaff, M.D.
Radiologist
Airway Outpatient Center
57463 29 Palms Hwy, Suite #206
Yucca Valley, CA 92284

W/L Number: 68 - 01
Inspection ID: 1005110007
CFN: 20-29,450
FEI: 1000518797

Dear Dr. Pfaff:

We are writing to you because on June 21, 2001 your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Processor quality control (QC) records in the month of August 2000 were missing for ten (10) out of that month's twenty-three (23) operating days (forty-three percent [43%] of the time) for processor #1 (a [REDACTED] machine, model [REDACTED]) which is located in the darkroom. During this time period, the processor was used to develop patient mammograms.

- Level 1: Processor QC records were missing for nine (9) consecutive days during the month of August 2000 for processor #1 (a [REDACTED] machine, model [REDACTED]) which is located in the darkroom. During this time period, the processor was used to develop patient mammograms.

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re: Airway Outpatient Center
re: Warning Letter Number 68 - 01

The specific problems noted on the previous page appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the **repeated** Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

- Level 2: Failed to produce documents verifying that the radiologic technologist, [REDACTED], (fourteen [14] CEU's in thirty-six [36] months) met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in 36 months. This is a **REPEAT** violation.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

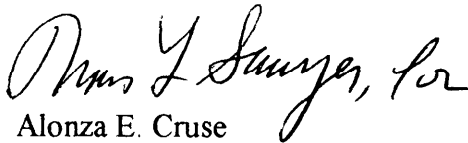
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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number 1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alonza E. Cruse, for".

Alonza E. Cruse
District Director

cc:

State of California
Department of Health Services
Radiological Health Branch
10605 Balboa Blvd.; Suite #315
Granada Hills, CA 91344-6342